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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/577,197	04/27/2006	Peter Gruber	104710-57195 (BHC 051012)	1409

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GIBBONS P.C.
ONE GATEWAY CENTER
NEWARK, NJ 07102

EXAMINER	
LEA, CHRISTOPHER RAYMOND	
ART UNIT	PAPER NUMBER
1619	

NOTIFICATION DATE	DELIVERY MODE
12/23/2008	ELECTRONIC

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

thibbits@gibbonslaw.com
abriggs@gibbonslaw.com
IPDocket@gibbonslaw.com

Office Action Summary	Application No.	Applicant(s)	
	10/577,197	GRUBER ET AL.	
	Examiner	Art Unit	
	Christopher R. Lea	1619	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☐ Responsive to communication(s) filed on _____.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-41* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-41* is/are rejected.

7)☒ Claim(s) *1,11-13,16,20,24,25,27,31 and 41* is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *27 April 2006* is/are: a)☒ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☒ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☒ All b)☐ Some * c)☐ None of:

1.☒ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *04/27/2006*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

This application is a 371 (national stage application) of PCT/CH04/00655.

Claims 1-41 are pending. Claims 1-41 are under examination.

Priority

1. If applicant desires to claim the benefit of a prior-filed application under 35 U.S.C. 120, a specific reference to the prior-filed application in compliance with 37 CFR 1.78(a) must be included in the first sentence(s) of the specification following the title or in an application data sheet. For benefit claims under 35 U.S.C. 120, 121 or 365(c), the reference must include the relationship (i.e., continuation, divisional, or continuation-in-part) of the applications.

If the instant application is a utility or plant application filed under 35 U.S.C. 111(a) on or after November 29, 2000, the specific reference must be submitted during the pendency of the application and within the later of four months from the actual filing date of the application or sixteen months from the filing date of the prior application. If the application is a utility or plant application which entered the national stage from an international application filed on or after November 29, 2000, after compliance with 35 U.S.C. 371, the specific reference must be submitted during the pendency of the application and within the later of four months from the date on which the national stage commenced under 35 U.S.C. 371(b) or (f) or sixteen months from the filing date of the prior application. See 37 CFR 1.78(a)(2)(ii) and (a)(5)(ii). This time period is not extendable and a failure to submit the reference required by 35 U.S.C. 119(e) and/or

120, where applicable, within this time period is considered a waiver of any benefit of such prior application(s) under 35 U.S.C. 119(e), 120, 121 and 365(c). A benefit claim filed after the required time period may be accepted if it is accompanied by a grantable petition to accept an unintentionally delayed benefit claim under 35 U.S.C. 119(e), 120, 121 and 365(c). The petition must be accompanied by (1) the reference required by 35 U.S.C. 120 or 119(e) and 37 CFR 1.78(a)(2) or (a)(5) to the prior application (unless previously submitted), (2) a surcharge under 37 CFR 1.17(t), and (3) a statement that the entire delay between the date the claim was due under 37 CFR 1.78(a)(2) or (a)(5) and the date the claim was filed was unintentional. The Director may require additional information where there is a question whether the delay was unintentional. The petition should be addressed to: Mail Stop Petition, Commissioner for Patents, P.O. Box 1450, Alexandria, Virginia 22313-1450.

If the reference to the prior application was previously submitted within the time period set forth in 37 CFR 1.78(a), but not in the first sentence(s) of the specification or an application data sheet (ADS) as required by 37 CFR 1.78(a) (e.g., if the reference was submitted in an oath or declaration or the application transmittal letter), and the information concerning the benefit claim was recognized by the Office as shown by its inclusion on the first filing receipt, the petition under 37 CFR 1.78(a) and the surcharge under 37 CFR 1.17(t) are not required. Applicant is still required to submit the reference in compliance with 37 CFR 1.78(a) by filing an amendment to the first sentence(s) of the specification or an ADS. See MPEP § 201.11.

2. Receipt is acknowledged of a certified copy of the CH1848/03 application referred to in the oath or declaration or in an application data sheet. If this copy is being filed to obtain the benefits of the foreign filing date under 35 U.S.C. 119(a)-(d), applicant should also file a claim for such priority as required by 35 U.S.C. 119(b). If the application being examined is an original application filed under 35 U.S.C. 111(a) (other than a design application) on or after November 29, 2000, the claim for priority must be presented during the pendency of the application, and within the later of four months from the actual filing date of the application or sixteen months from the filing date of the prior foreign application. See 37 CFR 1.55(a)(1)(i). If the application being examined has entered the national stage from an international application filed on or after November 29, 2000, after compliance with 35 U.S.C. 371, the claim for priority must be made during the pendency of the application and within the time limit set forth in the PCT and Regulations of the PCT. See 37 CFR 1.55(a)(1)(ii). Any claim for priority under 35 U.S.C. 119(a)-(d) or (f) or 365(a) or (b) not presented within the time period set forth in 37 CFR 1.55(a)(1) is considered to have been waived. If a claim for foreign priority is presented after the time period set forth in 37 CFR 1.55(a)(1), the claim may be accepted if the claim properly identifies the prior foreign application and is accompanied by a grantable petition to accept an unintentionally delayed claim for priority. See 37 CFR 1.55(c).

Information Disclosure Statement

3. The information disclosure statement(s) (IDS) submitted on April 27, 2006, was filed before the mailing date of the first office action on the merits. The submission is in compliance with the provisions of 37 CFR 1.97 & 1.98. Accordingly, the information disclosure statement is being considered by the examiner.

Oath/Declaration

4. Examiner notes the presence of two oath/declarations in the instant application. The first declaration (generated as part of PCT/CH2004/00655) is properly executed but makes claims to neither foreign priority under 35 USC 119(a)-(d) nor domestic benefit under 35 USC 119(e) or 35 USC 120. The second declaration makes a claim of foreign priority to application 1848/03 filed October 30, 2003, in Switzerland; however this declaration is unexecuted. As such the second declaration is objected to for being improperly executed in accordance with either 37 CFR §§ 1.66 or 1.68.

Specification

5. The lengthy specification has not been checked to the extent necessary to determine the presence of all possible minor errors. Applicant's cooperation is requested in correcting any errors of which applicant may become aware in the specification.

Claim Objections

6. Claims 1, 11-13, 16, 20, 24, 25, 27, 31, & 41 are objected to because of the following informalities:

Claims 1 & 41 recite the term "if desired"; please amend this to “optionally".

Claims 11-13, 16, 20, 24, 25, 27, & 31 contain improper Markush language; proper Markush language is “…selected from the group consisting of…”.

In claim 41, the word "of" is needed between “mixture” and “the sodium naproxen" in line 6 of the claim.

Appropriate correction is required.

Claim Rejections - 35 USC § 112

7. The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

8. Claims 7-9 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 7 recites "wherein the auxiliary agent component comprises one or more basic auxiliary agents in a total quantity of at least 5% by weight, based on the weight of the tablet” which is indefinite. It is unclear whether the “total quantity” (which must be at least 5% of the tablet as a whole) is the total quantity of the auxiliary agent component or the total quantity of the one or more basic auxiliary agents. Claims 8 &9 contain similar constructions which are likewise indefinite. For the purposes of examination,

examiner is interpreting the claims such that "total quantity" refers to the total quantity of the auxiliary agent component.

Claim Rejections - 35 USC § 103

9. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

10. The factual inquiries set forth in *Graham* **v.** *John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

11. This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

12. Claims 1-29 & 33-41 are rejected under 35 U.S.C. 103(a) as being unpatentable over Kuramoto et al. (US Patent 5,470,580) in view of Panoz et al. (US Patent 5,051,262).

Applicant claims

Applicant claims a non-effervescent tablet that comprises sodium naproxen and a basic auxiliary agent. Applicant further claims excipients added to the tablet as well as percentages for several of the components.

Determination of the scope and content of the prior art (MPEP 2141.01)

Kuramoto et al. teach, as a whole, tablets containing naproxen sodium.

Claims 1-4, 7-13: Kuramoto et al. teach a tablet containing sodium naproxen in an of 80-90% and 2-20% auxiliary components (column 7, lines 32-44). Kuramoto et al. also teach that the tablet may optionally be film-coated (column 8, line 35).

Claims 5 & 6: Kuramoto et al. teach a water content of 6-8% (column 7, lines 32-44).

Claims 14-25: Kuramoto et al. teach povidone (non-crosslinked polyvinylpyrrolidone) and starch as binders (fillers) in the tablet (column 5, lines 11-34). Kuramoto et al. teach using 1-6% binder (filler) in the tablet (column 7, lines 32-44). The proportions claimed outside this range are not so disparate that the skilled artisan would expect different properties to be imparted to the composition as a whole.

Claims 26 & 27: Kuramoto et al. teach using croscarmellose as a disintegrant in the tablet (column 5, lines 43-45).

Claim 28: Kuramoto et al. teach including a lubricant and/or glidant in the tablet composition (column 5, lines 55-57).

Claim 29: Kuramoto et al. teach that lubricants/glidants are not essential to the invention, thereby teaching possible embodiments that contain not lubricant or glidant (column 7, lines 45-56).

Claim 33: Kuramoto et al. teach a tablet with granule size of 100-350 microns (.1 to .35 mm) (example 1, column 9, line 10).

Claim 34: Kuramoto et al. teach a tablet with hardness of at least 5 S.C. units (35 N) (example 1, column 9, line 11-12).

Claim 35: The claimed amount of the active agent component is a result-effective parameter chosen to obtain the desired effects and controllable through the size of the tablet made, all of which are within the purview of the skilled artisan to determine.

Claim 36: Kuramoto et al. teach that the tablet may consist essentially of 100% naproxen sodium (column 7, lines 45-56).

Claims 37-40: Kuramoto et al. teach naproxen sodium tablets comprising *inter alia* microcrystalline cellulose, croscarmellose (both column 5, lines 43-45), talc, and magnesium stearate (column 5, lines 55-57). Kuramoto et al. teach water-soluble cellulose derivatives, such as a hydroxypropyl cellulose, as suitable binders (column 5, lines 11-15). The claimed amounts and proportions of the auxiliary agent components are result-effective parameters chosen to obtain the desired effects and optimizable through routine experimentation.

Claim 41: Kuramoto et al. teach a method of making a tablet where naproxen sodium (80-90%) is combined with auxiliary agent components and compressed into a tablet (claim 7).

Ascertainment of the difference between the prior art and the claims (MPEP 2141.02)

The difference between the teachings of Kuramoto et al. and the instant claims is that Kuramoto et al. do not teach adding a basic auxiliary agent to the tablet. This deficiency in Kuramoto et al. is cured by the teachings of Panoz et al.

Panoz et al. teach, as a whole, adding pH adjustors to active agents to improve the release of the agents.

Claims 1-41: Panoz et al. teach adding pH-adjusting compounds to dosage forms, thereby creating a microenvironment around the medicament, causing the medicament to have optimum solubility independent of the pH of the surrounding region of the gastro-intestinal tract (column 2, lines 56-65). Panoz et al. teach naproxen among the drugs that would benefit from the addition of a basic pH adjustor (column 5, lines 41-56). Panoz et al. teach alkaline bicarbonates (which include sodium hydrogen carbonate) among the basic pH adjustors (column 5, lines 57-65). The claimed amounts and proportions of the basic auxiliary agent are result-effective parameters chosen to obtain the desired effects.

Finding of *prima facie* obviousness
Rationale and Motivation (MPEP 2142-2143)

It would have been *prima facie* obvious to one of ordinary skill in the art at the time the claimed invention was made to add a basic auxiliary agent (such as sodium hydrogen carbonate) as taught by Panoz et al. to the naproxen tablets taught by Kuramoto et al. to improve the solubility of the naproxen and produce the instant invention. The skilled artisan would have been motivated to do this because Panoz et al. teach naproxen among the drugs that would benefit from the addition of a basic pH adjustor.

From the teachings of the references and in the absence of evidence to the contrary, it is apparent that one of ordinary skill in the art would have had a reasonable expectation of success in adding sodium hydrogen carbonate to the naproxen sodium tablet and producing the claimed invention. Therefore, the invention as a whole would have been *prima facie* obvious to one of ordinary skill in the art at the time the invention was made, as evidenced by the references, especially in the absence of evidence to the contrary.

13. Claims 30-32 are rejected under 35 U.S.C. 103(a) as being unpatentable over Kuramoto et al. and Panoz et al. as applied to claim 1 above, and further in view of Patel et al. (US PreGrant Publication 2003/0180352).

Applicant claims

Applicant claims a tablet containing naproxen sodium and a basic auxiliary agent further comprising a tenside (surfactant).

Determination of the scope and content of the prior art (MPEP 2141.01)

Since claims 30-32 depend from claim 1, rejection of claim 1 under 35 USC 103 is also appropriate. Detailed discussion of the rejection of claim 1 and the teachings of Kuramoto et al. and Panoz et al. appears above.

Ascertainment of the difference between the prior art and the claims (MPEP 2141.02)

The difference between the combined teachings of Kuramoto et al. and Panoz et al. and the instant claims is that Kuramoto et al. and Panoz et al. do not teach adding a surfactant to the tablet. This deficiency in Kuramoto et al. and Panoz et al. is cured by the teachings of Patel et al.

Patel et al. teach, as a whole, solid carriers for improved delivery of active agents in pharmaceutical compositions.

Patel et al. teach adding ionic and/or non-ionic surfactants to solid dosage forms as means to improve the stability and dissolution profile of the active agent (paragraph 144). Among the preferred ionic surfactants taught by Patel et al. is sodium lauryl (dodecyl) sulfate (paragraph 191). The claimed amounts and proportions of the tenside (surfactants) are result-effective parameters chosen to obtain the desired effects.

Finding of *prima facie* obviousness Rationale and Motivation (MPEP 2142-2143)

It would have been *prima facie* obvious to one of ordinary skill in the art at the time the claimed invention was made to add a surfactant as taught by Patel et al. to the tablet taught by the combination of Kuramoto et al. and Panoz et al. to improve the solubility and bioavailability of the active agent and produce the instant invention. The skilled artisan would have been motivated to ass a surfactant because Patel et al. teach that adding a surfactant to solid dosage form can provide increased solubility of the active ingredient in the solid carrier; improved dissolution of the active ingredient; improved solubilization of the active ingredient upon dissolution; enhanced absorption and/or bioavailability of the active ingredient, particularly a hydrophilic active ingredient; and improved stability, both physical and chemical, of the active ingredient..

From the teachings of the references and in the absence of teachings to the contrary, it is apparent that one of ordinary skill in the art would have had a reasonable expectation of success in adding a surfactant to the tablet containing naproxen sodium and a basic auxiliary agent and producing the claimed invention. Therefore, the invention as a whole would have been *prima facie* obvious to one of ordinary skill in the art at the time the invention was made, as evidenced by the references, especially in the absence of evidence to the contrary.

Conclusion

Claims 1-41 are rejected. Claims 1, 11-13, 16, 20, 24, 25, 27, 31, & 41 are objected to. No claims are allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Christopher R. Lea whose telephone number is (571)270-5870. The examiner can normally be reached on Mon-Thu 7:30-5:00 ET.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Johann Richter can be reached on (571)272-0646. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

CRL

/Johann R. Richter/
Supervisory Patent Examiner, Art Unit 1616